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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,776	10/10/2001	Zhiwei Jiang	22596-514 (CO-14)	9481

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BOSTON, MA 02111

EXAMINER

KRASS, FREDERICK F

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 12/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/975,776

Applicant(s)

JIANG ET AL.

Examiner

Frederick F. Krass

Art Unit

1614

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 30 November 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 30 November 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☒ Applicant's reply has overcome the following rejection(s): 103 rejection with regard to claims 9,18,28,43,54,186 and 204-209.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: 9,18,28,43,54,186 and 204-209.Claim(s) rejected: 1,2,6,11,12,15,19,21,22,25,30-34,36,37,40,45-48,51,180 and 182-185.

Claim(s) withdrawn from consideration: _____

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____

Continuation of 5. does NOT place the application in condition for allowance for the following reasons:

Bodor (USP 4,983,586) clearly states at col. 75, line 46 that the characteristics of "suitable drugs" can be determined by "simple experiments". This directly- and factually - contradicts Applicant's assertions/opinions that the art is so unpredictable that no drugs other than those actually disclosed by Bodor et al could be used.

The examiner does agree, however, with the analysis provided at pages 16 and 17 of Applicant's remarks that unexpected results obtained with hydroxypropyl-beta-cyclodextrin can be reasonably representative of beta-cyclodextrins generally. But, as Applicant has argued therein, it is critical that the central, lipophilic cavity of the cyclodextrin molecule be able to complex with the water insoluble drug to provide the requisite stability. The instant claims are not commensurate in scope with the showings of unexpected results of record, however, since they are not limited to drugs which meet that requirement. One could in no way predict if an unspecified "analog" of beta-lapachone would meet that requirement, for example.

Based on this analysis, the examiner has reconsidered the allowability of claims 9, 18, 28, 43, 54, 186 and 204-209, and these claims are now objected to. (See boxes number "5" and "7" above). These claims would be allowable if rewritten to include the limitations of any intervening claims, because they are limited to the species B-lapachone, which was actually tested by Applicant, and for which unexpected results have been demonstrated.

FREDERICK A. KAPLAN
PRIMARY EXAMINER
GROUP 1600

